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Before the
Federal Communications Commission
Washington, D.C. 20554

Petition to Amend the Medical Implant Communications Service (MICS) Rules to Add Inductive Telemetry at 90-110 kHz, Expand the MICS Spectrum and Make Other Technical Changes in MICS	)))))	RM-

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Federal Communications Commission
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Petition for Rulemaking

Guidant Corporation (Guidant) hereby requests that the Office of Engineering and Technology (OET) propose, in its upcoming Notice of Proposed Rulemaking on radiofrequency medical devices,[1] to amend Part 95 rules for the Medical Implant Communications Service (MICS) to include medical implant devices that use inductive telemetry in the 90-110 kHz band.

Background

Guidant is a leading worldwide manufacturer of medical devices for cardiac patients. It has been manufacturing implantable devices with "communications features" since the early 1960s. Guidant heart devices include implantable pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices. Historically, these devices have used inductive coupling to communicate heart information between patients and doctors. Inductive coupling has been a cost effective solution for early generations of implants due to the relatively small form factor and low energy requirements of this technology. An undesired by-product of inductively-coupled implants is that they produce very low levels of radiated

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[1] *See* Telecommunications Reports, February 1, 2006 at 34. OET has announced that it is preparing a comprehensive review of rules involving the spectrum needs of advanced medical technologies.

emissions across several frequency bands, including, in some instances, the 90-110 kHz band, which is a restricted band under Section 15.205.[2]

Guidant's next generation of implants will feature an advanced ICD design that will include an expanded memory and high-speed two-way communications. These new devices will store and download larger quantities of heart rhythm data for improved patient care. As doctors demand even higher speed delivery of increasing amounts of implant information, the need for additional spectrum will continue to grow. Moreover, as implant patient populations expand and other medical therapies move into implant arenas, spectrum availability and interference among devices will become pressing regulatory concerns. One look at today's MICS rules and it is clear that they are inadequate to meet these future demands. Thus, the spectrum allocated to MICS needs to be expanded substantially and the technical rules overhauled.

I. Inductive Medical Telemetry Applications Should be Included in MICS

Currently, there are millions of people with implants in all walks of life who depend on inductive telemetry to communicate heart rhythm data to their doctors. In the typical case, an implanted pulse generator (PG) collects real-time or stored heart data, which is communicated to a programmer-reader monitor (PRM) via handheld wand. Downloading is initiated by the PRM wand held in contact with, or very close to, the patient's chest while a pulsed magnetic field is induced at low frequency (*e.g.*, 40-50 kHz). When the PG senses the field, it responds by modulating its own magnetic field with encoded data. Implant data downloaded in this fashion can take 20 minutes or longer, depending on how much information is stored in the PG and retrieved by the PRM.

During the initiation[3] and downloading process, undesired radiated emissions are generated by the induction process. Typically, however, the energy levels of these emissions are 50-90 dB below the Commission's general Part 15 limits for intentional radiators and present no possible

[2] The 90-110 kHz band is restricted because it is assigned for navigational use (*i.e.*, Loran C). Any unlicensed device approved under Part 15 may only emit spurious energy in a restricted band.

[3] The initiation "handshake" is important in order to assure patient security. Transmissions between PG and wand must be within six inches to guarantee that the responding implant is the intended target of PRM communication.

devices were meant to be included in the new definition.[8] When the first Report & Order was released in 1989, however, the Commission, without explanation, changed the wording in its proposed definition of intentional radiator by removing of the words "over the air" and substituting the words "by radiation or induction."[9] No comments filed in the docket had called for such expansion of Commission jurisdiction. Thus, the new rule was implemented without prior notice or opportunity for industry comment. The net effect was to bring many types of previously unregulated devices into the Commission's equipment authorization program for the very first time.

It was also during the Part 15 Rewrite that the U.S. Coast Guard requested that the 90-110 kHz Loran C band be added to the list of "restricted" bands to protect users from possible harmful interference from unlicensed devices.[10] The Commission granted the Coast Guard's request and added the band, along with several others, to the restricted list, which now appears in Section 15.205. At the same time the Commission expand the restricted list, it made another key change in the rules that affected the kinds of emissions that would be permitted in such bands from unlicensed devices. Before 1989, an unlicensed device could generate any type of emission (*i.e.*, fundamental or spurious) in a restricted band, provided it was at a reduced level.[11] Under the new rules, however, only spurious emissions would be permitted in the restricted bands and fundamental emissions would be barred entirely. No explanation was provided by the Commission as to whether newly-regulated induction devices were also meant to be targeted by this new scheme.[12]

Presumably, no one at the time thought the new restricted band rules applied to inductive implants. Had they applied, the impact would have been devastating because it would mean that if any emissions (regardless of how insignificant) fell into a restricted band, an implant could be

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[8] The NPRM defined "intentional radiators" as "devices that intentionally generate and transmit radio frequency energy over the air. Examples are walkie-talkies, garage door opener controls, security alarm devices, cordless telephones, etc."

[9] *See* First Report and Order, *Revision of Part 15 of the Rules Regarding the Operation of Radio Frequency Devices Without an Individual License*, Docket No. 87-389, FCC 89-103 at ¶ 16, 4 FCC Rcd 3493, 3495 (rel. April 18, 1989) ("Intentional Radiator. A device that intentionally generates and emits radio frequency energy by radiation or induction."). See Section 15.3(o) of the rules.

[10] See Section 15.205 of the rules.

[11] The restricted band limits, circa 1987 were 15uV/m at 3m.

[12] Arguably, induction devices generate only RF spurious (unintended) emissions.

outlawed under the new rules. Indeed, one must surely surmise that implant manufacturers, had they known that such changes were under consideration by the Commission, would have requested a grandfathering of these low power devices or, more likely, an exemption from the band restrictions that the Commission was granting to other devices at the time.[13]

Even today, it is still unclear how induction devices fit under the Commission's restricted band prohibition of Section 15.205. As noted, the rules permit only spurious emissions in these bands; but a spurious emission is defined by the Commission's rules as an emission "...outside the necessary bandwidth and the level of which may be reduced without affecting the corresponding transmission of information."[14] In an induction device, information is communicated not through the radiated energy field (which is purely a by-product of inductive coupling), but through the magnetic field which is pulsed or modulated with encoded data. While it would be expensive (and certainly useless) to suppress the radiation field, theoretically it could be done "without affecting the corresponding transmission of information."[15] Seen in this light, the radiated energy field from an inductive device squarely meets the definition of a "spurious emission" and is permitted to fall in the restricted bands. Nonetheless, given the regulatory uncertainty created by the Part 15 Rewrite, it is incumbent on the Commission to "clear the air" in a new rulemaking proceeding.[16]

2. MICS Should be Amended to Include 90-110 kHz Telemetry

At emission levels 50-90 dB below the general limits of Section 15.209, any concerns about implant interference to licensed radio (*i.e.*, Loran C) is largely academic. Indeed, the emissions from inductive implants are so far below the ambient noise floor that the PRM wand cannot receive them more than 6 inches from a patient's chest. Yet, because by-product radiated emissions from some implants fall within the 90-110 kHz restricted band, unlicensed operation

[13] Section 15.205(d), for instance, exempts transmitters for detecting telephone markers and cable locating equipment from the 90-110 kHz restricted band prohibitions.
[14] 47 C.F.R. § 2.1(c).
[15] *See Id.*
[16] The unclear regulatory status of medical implants using inductive communications is highlighted by the March 18, 1999 grant of equipment authorization to St Jude Medical CRMD for a cardiac implant device operating at 100 kHz. Even the Commission's Laboratory staff was not aware of the virtually unpublicized changes to Part 15 made ten years before.

under Part 15 raises theoretical questions of compliance with Commission rules. One solution would be to carve out a narrow exception to the Part 15 restricted band prohibitions for medical implants. This, however, creates possibly unwanted precedent for other medical devices that might not be as acceptable to federal users as heart implants.[17] A better solution, therefore, would be to amend the MICS rules to expressly include all implants, including those that operate inductively in the 90-110 kHz band. Inasmuch as inductive links will continue to serve a critical backup function in future generations of medical implants, it makes good "regulatory sense" to include all such devices under Part 95.[18]

Conclusion

For the reasons provided, Guidant respectfully requests that the Commission amend the Part 95 rules permit operation of inductive implants at 90-110 kHz. Such an amendment to the MICS rules will facilitate and improve patient health care by enabling the use of new generations of sophisticated medical implant telemetry technologies.

Respectfully Submitted,

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[17] Additional pressure to resolve this problem is a Petition for Waiver filed by Respironics, Inc. on October 28, 2005 (ET Docket No. 05-331). Respironics manufactures a device worn on the wrist to measure data associated with sleep disorders. This device also operates at 90-110 kHz.

[18] Inductive implants should only be governed by field strength limits. The MICS requirements for frequency monitoring, bandwidth, etc. should not apply to inductive devices.

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